ABSTRACT

Analytical method development and method validation has an imperative role in separation, identification, and estimation of pharmaceutical dosage forms. Many drugs either alone or in combination with one or more drugs are launched into the market every year and the standard procedures for analyzing the purity of these dosage forms are not available in the standard pharmacopoeias. Combined pharmaceutical dosage forms are gaining importance in the present days as they can produce combined therapeutic effect. Hence there is a need for developing new reliable analytical methods for quality control analysis of the new dosage forms marketed by the pharmaceutical companies. The quality, efficacy and safety of different pharmaceutical formulations are regularly monitored by standard regulatory bodies

The main focus of the undertaken research work is on the development of new, simple, faster and economical Reverse phase high performance liquid chromatographic (RP-HPLC) techniques for the estimation of novel pharmaceutical dosage forms and also focuses on the validation of the developed methods as per the INTERNATIONAL CONFERENCE ON HARMONIZATION (ICH) guidelines to render the methods feasible for application in quality control laboratories.

The drugs and drug combinations selected for the analysis are

Rimantadine Tablets marketed with brand name **FLUMADINE.**

Cidofovir Injection marketed with brand name **VISTIDE.**

Pranlukast Capsules marketed with brand name **ONON.**

Sofosbuvir and Velpatasvir tablets marketed with brand name **SOFOSVEL.**

Montelukast , Acebrophylline and Desloratadine combination tablets marketed with brand name **ACMON-DM.**

Pantoprazole, Chlorzoxazone and Diclofenac combination capsules marketed with brand name **ALLDEX-DT PLUS.**

The thesis entitled **“ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF DRUGS USING REVERSE PHASE HIGH**

PERFORMANCE LIQUID CHROMATOGRAPHIC TECHNIQUE" is divided into seven chapters.

Chapter 1 Introduction provides the overview of analytical chemistry and its role in drug analysis. It includes discussion on aim and objective of the undertaken work and the importance of RP-HPLC method development and validation and need for the study.

Chapter 2 Literature survey provides detailed information on earlier RP-HPLC method development and their validation works carried by earlier researchers related to the selected drugs.

Chapter 3 describes Estimation and validation of Rimantadine Tablets, Cidofovir injection and Pranlukast capsules individually by RP-HPLC method in their respective dosage forms.

Chapter 4 deals with the Simultaneous estimation of Sofosbuvir and Velpatasvir Tablets by RP-HPLC method and its validation.

Chapter 5 includes Simultaneous estimation of Montelukast, Acebrophylline and Desloratadine combination Tablets by RP-HPLC method and its validation.

Chapter 6 Simultaneous estimation of Pantoprazole, Chlorzoxazone and Diclofenac combination capsules by RP-HPLC method and its Validation was discussed in this chapter.

All the validation parameters of individual and multi component drugs were studied in the present investigation by RP –HPLC technique.

Chapter 7 Summary, conclusion and recommendations illustrates the overall summary, conclusion and future recommendations of the present research work conducted.

REFERENCES provide the details of research articles referred in designing and performing the investigation.